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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,500	03/11/2005	Jesus G Valenzuela	4239-66903-02	9994

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KLARQUIST SPARKMAN, LLP
121 S.W. SALMON STREET
SUITE #1600
PORTLAND, OR 97204-2988

EXAMINER	
ARCHIE, NINA	
ART UNIT	**PAPER NUMBER**
1645	

MAIL DATE	DELIVERY MODE
10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,500	VALENZUELA ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 25-37* is/are pending in the application.

4a) Of the above claim(s) *8-20 and 26-37* is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7 and 25* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Information Disclosure Statement

2. The information disclosure statement filed on 3/11/2005, 7/1/2005, 1/11/2006, 5/15/2006, and 9/7/2007 has been considered. Initialed copies are enclosed.

Election/Restrictions

3. Applicant's election with traverse of Group 1 claims 1-7 and 25 is acknowledged. According to PCT Rule 13.1 and 13.2. The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The traversal is on the ground(s) that Groups I through IV are linked to form a single general inventive concept. The invention as claimed relates to a substantially purified salivary P. ariasi polypeptide (Group I). The claimed invention further relates to nucleic acid sequences encoding the substantially purified salivary P. ariasi polypeptide (Group II), and methods of using the substantially purified salivary P. ariasi polypeptide (Groups III and IV). Thus, the special technical feature shared among all of the claims is the substantially purified salivary P. ariasi polypeptide. Moreover, as claims 1-20 and 25-37 (Groups I-IV) all depend, directly or indirectly, from claim 1 (thereby incorporating all of the limitations thereof), these claims all relate to the special technical feature of the

substantially purified salivary P. ariasi polypeptide of claim 1. Furthermore, this special technical feature does define a contribution over the prior art for each of the claimed inventions. There is no reference of record in the case that reads on the substantially purified salivary P. ariasi polypeptide, or its use. No reference has been cited in the current Restriction Requirement, which would appear to be a clear admission that there is no relevant prior art. Since the Office has provided neither allegation nor evidence that a substantially purified salivary P. ariasi polypeptide is disclosed or rendered obvious by the prior art, this feature clearly constitutes an appropriate "corresponding special technical feature" sufficient for the fulfillment of the unity of invention requirement [See 37 CFR § 1.475(a); MPEP § 1893.03(d)]. Finally, in the unlikely event that the Office determines that all of the Groups (and sequences) cannot be recombined, Applicants request that the claims of Group IV, directed to the method of inhibiting a symptom of a Leishmania infection or preventing a Leishmania infection in a subject using the polypeptide as set forth in SEQ ID NO: 11, be examined with the claims of Group I (directed to the polypeptide). The method claims depend from or otherwise include all the limitations of claims to the product. Applicants expressly request that the method claims be rejoined and the claims examined, at the latest upon the allowance of any of the product claims.

This is not found persuasive. The lack of unity dated on 6/15/07 is based on the claims filed. The special technical feature of Group 1 is a purified salivary *P. ariasi* polypeptide. Group II is drawn to the second technical feature, an isolated nucleic acid, vector, and host cell. Group III are drawn to a method of use of the first technical feature, a purified salivary *P. ariasi* polypeptide. Group IV are drawn to a method of use of the first technical feature, a purified salivary *P. ariasi* polypeptide. The special technical feature of Group 1 is anticipated by Valenzuela et al 2001 The Journal of Experimental Medicine Volume 194, No. 3 pgs. 331-342 as evidence by Oliveira et al 2006 Vaccine 24 pgs. 374-390. Valenzuela et al teach a salivary protein of *Phlebotomus papatasi* (see Abstract, pgs. 332-334 "Materials and Methods"). Oliveria et

al teach that there are homologous proteins in *Phlebotomus ariasi* and *Phlebotomus papatasi*. Therefore, unity of invention is lacking.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-20, 26-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions Group II (claims 8-20 and 26), Group III (claims 27-34), Group IV (claims 35-37) there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response filed 8-15-07.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 2, 5-7 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claim is drawn to a vast genus of the amino acid of SEQ ID NO:11. To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the

members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. To adequately describe the genus of the amino acid of SEQ ID NO:11, applicant must also give a functional limitation of amino acid SEQ ID NO: 11.

The specification, however, does not disclose distinguishing and identifying features of a representative member of the genus of the amino acid of SEQ ID NO:11 to which the claims are drawn, such as a correlation between structure of the peptide and its recited function, so that the skilled artisan could immediately envision or recognize at least a substantial number of members of the claimed genus of antigens.

MPEP § 2163.02 states, "an objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed". The courts have decided: The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed. See Vas-Cath, Inc.'v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, "'Written Description" Requirement (66 FR 1099-1111, January 5,2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was

complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (Id. at 1104).

The Guidelines further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus.

It is noted that applicant(s) have listed a sequence, which has a high percentage similarity to a claimed sequence. Absent factual evidence, a percentage sequence similarity of less than 100% is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of such a similar known biomolecule. It is known for nucleic acids as well as proteins, for example, that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. The effect of these changes are largely unpredictable as to which one have significant effect versus not. Therefore, the citation of sequence similarity results in an unpredictable and therefore unreliable correspondence between the claimed biomolecule and the indicated similar biomolecule of known function and therefore lacks support regarding utility and/or enablement. Several publications document this unpredictability of the relationship between sequence and function, albeit that certain specific sequence may be found to be conserved over biomolecules of related function upon a significant amount of further research. See the following publications that support this unpredictability as noting certain conserved sequences in limited specific cases: Gerhold et al [BioEssays, Vol.18, pages. 973-981 {1996}]. Therefore, in accordance with the Guidelines, the description of amino acids is not deemed representative of the genus amino acid of SEQ ID NO:11 of the claimed invention thus the claim does not meet the written description requirement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim~~s~~ 1~~-7~~ is rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs et al WO9920644 Date April 29, 1999.

Claim~~s~~ 1~~-7~~ are drawn to a substantially purified salivary *P. ariasi* polypeptide.

Jacobs et al teach an antigenic fragment of the polypeptide of SEQ ID NO: 11 (see STIC RESULTS).

Status of the Claims

6. Claims 1, 2, 4-7 and 25 are rejected.

Claim 3 is objected as being dependent from a base claim.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina Archie

Nina A Archie
Examiner
GAU 1645
REM 3B31

MARK NAVARRO
PRIMARY EXAMINER

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/11/2005, 7/1/2005, 1/11/2006, 5/15/2006, 9/7/2007.